

REMARKS

Claims 1-4, 6, 9, 27 and 33-37 are pending. Non-elected claims 24, 26, 28, 30 and 32 were withdrawn from consideration by the Examiner. Applicants cancel the non-elected claims without prejudice to future prosecution of that subject matter. Amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Substitute paper and computer readable forms of the Sequence Listing are being submitted herewith in response to the Examiner's requirement. Sequence identifiers are inserted in the specification. The paper and computer readable forms of the Sequence Listing do not add new matter, and their contents are the same. A mis-translation in claim 6 is corrected by replacing "villous tumor" with --papilloma--.

It was alleged on page 3 of the Action that a certified copy of the priority document was not filed. Applicants provided a certified copy to the Receiving Office under PCT Rule 17. Its receipt by the International Bureau was acknowledged in the attached Notification. A copy should have been forwarded by WIPO to each of the designated offices. See also M.P.E.P. § 1893.03(c). Therefore, in accordance with M.P.E.P. § 1896 III, the Examiner is respectfully requested to consult with the Special Program Examiner in the Technology Center to obtain a certified copy of the priority document. Also see PCT Rule 17.2 which states, "No such Office shall ask the applicant himself to furnish it with a copy." Acknowledgement is requested that the priority document was received.

35 U.S.C. 101 –Utility

Claims 1-2, 4-5, 8, 23, 25 and 33-34 were rejected under Section 101 because they are allegedly "directed to non-statutory subject matter." Applicants traverse as the present amendments moot this objection.

Withdrawal of the Section 101 rejection is requested.

35 U.S.C. 112 – Enablement and Written Description

Claims 4-10, 23, 25, 29 and 31 were rejected under Section 112, first paragraph, because it was alleged that the specification "does not reasonably provide enablement for a therapeutic agent for treating a disease that is able to ameliorated by enhancing

type I interferon production, said agent comprising a cell comprising a vector that is comprised a gene encoding the polypeptide of SEQ ID NO:2." Applicants traverse.

It was alleged on page 4 of the Action, "Claims 4-10 are drawn to a therapeutic agent for treating unidentified diseases." In response, Applicants have amended claims 4, 6 and 9 to specify that the treated disease is cancer. It is found that dendritic cells of TICAM-1 gene deficient mice cannot activate NK cells and, therefore, antitumor activity is reduced. See Akazawa et al. references: PNAS, 104:252-257 (2007) and FEBS Lett., 581:3334-3340 (2007). Therefore, treatment of cancer by the claimed invention does not require undue experimentation.

The other objections applying to claims 5, 7-8, 10, 23, 25, 29 and 31 are mooted by their cancellation.

Claims 23, 25, 29 and 31 were rejected under Section 112, first paragraph, as allegedly "failing to comply with the written description requirement." Applicants traverse because, as noted above, cancellation of claims 23, 25, 29 and 31 moots the objection.

Withdrawal of the Section 112, first paragraph, rejections is requested.

35 U.S.C. 112 – Definiteness

Claims 4-6 were rejected under Section 112, second paragraph, as allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse because the claims as amended are clear and definite.

Claims 3-6 were rejected under Section 112, second paragraph, as allegedly "the recitation of the intended use, does not further limit the structure recited in claim 1." Applicants traverse because the claims as amended are directed to methods instead of the intended use of a product.

The claims are rewritten in idiomatic English as required by the Examiner. This includes correction of a mistranslation of claim 6.

Withdrawal of the Section 112, second paragraph, rejections is requested.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-10 were rejected under Section 102(b) as allegedly anticipated by Lal et al. (WO-00/78954-A2). Applicants traverse because Lal does not teach the limitations required by the claims as amended.

Lal neither discloses nor suggests that production of Type I interferon is strongly enhanced by introducing a recombinant expression vector containing a gene encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2 to a cell in which the Toll-like receptor 3 is expressed. Therefore, the amended method claims could not have been conceived by a person skilled in the art based on Lal's disclosure.

Claims 1-10 were rejected under Section 102(b) as allegedly anticipated by Accession Number O75532. Applicants traverse because the cited database entry does not teach the limitations required by the claims as amended.

Accession Number O75532 neither discloses nor suggests that production of Type I interferon is strongly enhanced by introducing a recombinant expression vector containing a gene encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2 to a cell in which the Toll-like receptor 3 is expressed. Therefore, the amended method claims could not have been conceived by a person skilled in the art based on the database entry of Accession Number O75532.

Claims 1-10, 23, 25, 27, 29, 31 and 33-36 were rejected under Section 102(b) as allegedly anticipated by Matsuda et al. (WO-02/53737-A1). Applicants traverse because Matsuda does not teach the limitations required by the claims as amended.

Matsuda discloses a large number of proteins, which each activate NF- κ B when a gene encoding the protein is introduced and expressed in a cell. Out of the proteins, the amino acid sequence set forth in SEQ ID NO: 154 is the same as the amino acid sequence set forth in SEQ ID NO: 2 of the present application. Further, a "compound for

inhibiting or promoting activation of NF-κB screened with use of a protein having the effect of activating NF-κB,” an “antibody specifically binding to a protein having the effect of activating NF-κB,” and an “antisense oligonucleotide for a gene encoding a protein having the effect of activating NF-κB” are disclosed as effective as a therapeutic agent for treating or preventing diseases caused by undesirable activation of NF-κB.

Matsuda discloses a cell to which a recombinant expression vector that contains a gene encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2 of the present application is introduced. But Matsuda neither teaches nor suggests that a Toll-like receptor 3 is expressed in the cell. Therefore, claims 1 and 3-4 of the present application could not have been conceived by a person skilled in the art based on Matsuda’s disclosure. Further, Matsuda neither discloses nor suggests that production of type I interferon is strongly enhanced by introducing a recombinant expression vector containing a gene encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 2 of the present application to a cell. Therefore, claims 1, 3-4 and 9 of the present application could not have been conceived by a person skilled in the art based on Matsuda’s disclosure.

Withdrawal of the Section 102 rejections is requested.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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PATENT COOPERATION TREATY

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**NOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT**

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 30 March 2004 (30.03.2004)	From the INTERNATIONAL BUREAU	
Applicant's or agent's file reference A211-02/PCT	To:	
International application No. PCT/JP2003/014854	HARA, Kenzo HARAKENZO PATENT LAW FIRM Daiwa Minamimorimachi Building 2-6, Tenjinbashi 2-chome Kita, Kita-ku Osaka-shi, Osaka 530-0041	RECEIVED APR 12 2004 HARA KENZO PATENT
International publication date (day/month/year) Not yet published	IMPORTANT NOTIFICATION	
Priority date (day/month/year) 29 November 2002 (29.11.2002)		
Applicant JAPAN SCIENCE AND TECHNOLOGY AGENCY et al		

- By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- (If applicable) The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
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Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
29 Nove 2002 (29.11.2002)	2002-349015	JP	18 Marc 2004 (18.03.2004)

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